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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 097613,591 | 07/10/00 | BOYLE | W A-378CIP5 |

021069
AMGEN INCORPORATED
MAIL STOP 27-4-A
ONE AMGEN CENTER DRIVE
THOUSAND OAKS CA 91320-1799

HM11/0724

EXAMINER
DEBERRY, R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1647 | 12 |

DATE MAILED: 07/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, DC 20231
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|---------------------------------|-------------|---|---------------------|
| APPLICATION NO./ CONTROL NO. | FILING DATE | FIRST NAMED INVENTOR / PATENT IN REEXAMINATION | ATTORNEY DOCKET NO. |
|---------------------------------|-------------|---|---------------------|

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| EXAMINER |
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| ART UNIT | PAPER |
|----------|-------|

12

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents

The communication filed 21 May 2001 is not fully responsive to the Office communication mailed 24 April 2001 for the reason(s) set forth on the attached Notice To Comply With The Sequence Rules or CRF Diskette Problem Report. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Since the reply appears to be bona fide attempt to comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825), applicant is given a TIME PERIOD of **ONE (1) MONTH** from the mailing date of this communication within which to correct the deficiency so as to comply with the sequence rules (37 CFR 1.821 - 1.825) in order to avoid abandonment of the application under 37 CFR 1.821(g). EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Any inquiry concerning this communication should be directed to Examiner **Regina M. DeBerry**, Art Unit 1647, whose telephone number is (703) 305-6915.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

ELIZABETH KEMMERER
PRIMARY EXAMINER

Notice to Comply

Application No.

09/613,591

Examiner

Regina M. DeBerry

Applicant(s)

BOYLE ET AL.

Art Unit

1647

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other:

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support

Technical Assistance.....703-287-0200

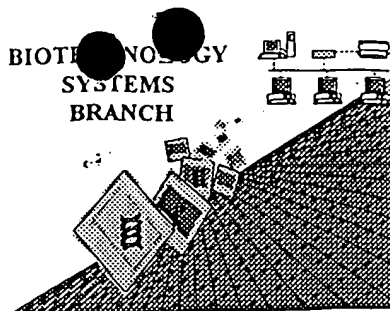
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

2. DePerry

RAW SEQUENCE LISTING ERROR REPORT

BIOTECHNOLOGY
SYSTEMS
BRANCH



Entered
7/19/01
RMD
Paper No.
1Z

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 09/613,591B

Source: 01PE

Date Processed by STIC: 6/5/2001

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.

PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

FOR SEQUENCE RULES INTERPRETATION, PLEASE CONTACT ROBERT WAX, 703-308-4216.

PATENTIN 2.1 e-mail help: patin21help@uspto.gov or phone 703-306-4119 (R. Wax)

PATENTIN 3.0 e-mail help: patin3help@uspto.gov or phone 703-306-4119 (R. Wax)

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 3.0 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW:

Checker Version 3.0

The Checker Version 3.0 application is a state-of-the-art Windows based software program employing a logical and intuitive user-interface to check whether a sequence listing is in compliance with format and content rules. Checker Version 3.0 works for sequence listings generated for the original version of 37 CFR §§1.821 - 1.825 effective October 1, 1990 (old rules) and the revised version (new rules) effective July 1, 1998 as well as World Intellectual Property Organization (WIPO) Standard ST.25.

Checker Version 3.0 replaces the previous DOS-based version of Checker, and is Y2K-compliant. Checker allows public users to check sequence listings in Computer Readable form (CRF) before submitting them to the United States Patent and Trademark Office (USPTO). Use of Checker prior to filing the sequence listing is expected to result in fewer errored sequence listings, thus saving time and money.

Checker Version 3.0 can be down loaded from the USPTO website at the following address:

<http://www.uspto.gov/web/offices/pac/checker>

OIPE

RAW SEQUENCE LISTING

DATE: 06/05/2001

PATENT APPLICATION: US/09/613,591B

TIME: 12:57:12

Input Set : A:\A-378CIP5.ST25.txt

Output Set: C:\CRF3\06052001\I613591B.raw

Does Not Comply
Corrected Diskette Needed

3 <110> APPLICANT: BOYLE, WILLIAM
 4 LACEY, DAVID
 5 CALZONE, FRANK
 6 CHANG, MING-SHI
 7 SENALDI, GIORGIO
 9 <120> TITLE OF INVENTION: COMBINATION THERAPY FOR CONDITIONS LEADING TO BONE LOSS
 11 <130> FILE REFERENCE: A-378CIP5
 13 <140> CURRENT APPLICATION NUMBER: US 09/613,591B
 14 <141> CURRENT FILING DATE: 2000-07-10
 16 <150> PRIOR APPLICATION NUMBER: US 09/457,647
 17 <151> PRIOR FILING DATE: 1999-12-09
 19 <150> PRIOR APPLICATION NUMBER: US 09/350,670
 20 <151> PRIOR FILING DATE: 1999-07-09
 22 <150> PRIOR APPLICATION NUMBER: US 08/706,945
 23 <151> PRIOR FILING DATE: 1996-09-03
 25 <150> PRIOR APPLICATION NUMBER: US 08/577,788
 26 <151> PRIOR FILING DATE: 1995-12-22
 28 <160> NUMBER OF SEQ ID NOS: 168
 30 <170> SOFTWARE: PatentIn version 3.0
 32 <210> SEQ ID NO: 1
 33 <211> LENGTH: 36
 34 <212> TYPE: DNA
 35 <213> ORGANISM: Artificial
 37 <220> FEATURE:
 38 <223> OTHER INFORMATION: Random cDNA with internal NotI restriction site.
 40 <220> FEATURE:
 41 <221> NAME/KEY: misc_feature *h's are not at these locations*
 42 <222> LOCATION: ((16, 17, 18, 19, 20, 21, 22 and) .. (23) *these are the correct locations*
 43 <223> OTHER INFORMATION: N = any random nucleic acid
 46 <400> SEQUENCE: 1

ENTERED

W--> 47 aaaggaagga aaaaagcggc cgctacannn nnnnt 36
 50 <210> SEQ ID NO: 2
 51 <211> LENGTH: 16
 52 <212> TYPE: DNA
 53 <213> ORGANISM: Artificial
 55 <220> FEATURE:
 56 <223> OTHER INFORMATION: ds oligonucleotide adapter
 58 <400> SEQUENCE: 2
 59 tcgaccacg cgtccg 16
 62 <210> SEQ ID NO: 3
 63 <211> LENGTH: 12
 64 <212> TYPE: DNA
 65 <213> ORGANISM: Artificial
 67 <220> FEATURE:
 68 <223> OTHER INFORMATION: ds oligonucleotide adapter
 70 <400> SEQUENCE: 3
 71 gggtgcgcag gc 12

RAW SEQUENCE LISTING

PATENT APPLICATION: US/09/613,591B

DATE: 06/05/2001

TIME: 12:57:12

Input Set : A:\A-378CIP5.ST25.txt

Output Set: C:\CRF3\06052001\I613591B.raw

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 76 <212> TYPE: DNA
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 79 <220> FEATURE:
 80 <223> OTHER INFORMATION: PCR primer
 82 <400> SEQUENCE: 4
 83 tgtaaaacga cggccagt 18
 86 <210> SEQ ID NO: 5
 87 <211> LENGTH: 18
 88 <212> TYPE: DNA
 OK-> 89 <213> ORGANISM: Artificial
 91 <220> FEATURE:
 92 <223> OTHER INFORMATION: PCR primer
 94 <400> SEQUENCE: 5
 95 caggaaacag ctatgacc 18
 98 <210> SEQ ID NO: 6
 99 <211> LENGTH: 20
 OK-> 100 <212> TYPE: DNA
 101 <213> ORGANISM: Artificial
 103 <220> FEATURE:
 104 <223> OTHER INFORMATION: T3 primer
 106 <400> SEQUENCE: 6
 107 caattaaccc tcactaaagg 20
 110 <210> SEQ ID NO: 7
 111 <211> LENGTH: 23
 112 <212> TYPE: DNA
 113 <213> ORGANISM: Rattus rattus
 115 <400> SEQUENCE: 7
 116 gcattatgac ccagaaaccg gac 23
 119 <210> SEQ ID NO: 8
 120 <211> LENGTH: 23
 121 <212> TYPE: DNA
 122 <213> ORGANISM: Rattus rattus
 124 <400> SEQUENCE: 8
 125 aggtagcgcc cttcctcaca ttc 23
 128 <210> SEQ ID NO: 9
 129 <211> LENGTH: 30
 OK-> 130 <212> TYPE: DNA
 131 <213> ORGANISM: Artificial
 133 <220> FEATURE:
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 136 <400> SEQUENCE: 9
 137 gactagtccc acaatgaaca agtggctgtg 30
 140 <210> SEQ ID NO: 10
 141 <211> LENGTH: 45
 142 <212> TYPE: DNA
 OK-> 143 <213> ORGANISM: Artificial
 145 <220> FEATURE:

RAW SEQUENCE LISTING

DATE: 06/05/2001

PATENT APPLICATION: US/09/613,591B

TIME: 12:57:12

Input Set : A:\A-378CIP5.ST25.txt

Output Set: C:\CRF3\06052001\I613591B.raw

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 149 ataagaatgc ggccgctaaa ctatgaaaca gcccagtgac cattc 45
 152 <210> SEQ ID NO: 11
 153 <211> LENGTH: 21
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 155 <213> ORGANISM: Artificial
 157 <220> FEATURE:
 158 <223> OTHER INFORMATION: PCR primer
 160 <400> SEQUENCE: 11
 161 gcctctagaa agagctggga c 21
 164 <210> SEQ ID NO: 12
 165 <211> LENGTH: 21
 166 <212> TYPE: DNA
 167 <213> ORGANISM: Artificial
 169 <220> FEATURE:
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 172 <400> SEQUENCE: 12
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 176 <210> SEQ ID NO: 13
 177 <211> LENGTH: 24
 178 <212> TYPE: DNA
 179 <213> ORGANISM: Rattus rattus
 181 <400> SEQUENCE: 13
 182 atcaaaggca gggcatactt cctg 24
 185 <210> SEQ ID NO: 14
 186 <211> LENGTH: 24
 187 <212> TYPE: DNA
 188 <213> ORGANISM: Rattus rattus
 190 <400> SEQUENCE: 14
 191 gttgcaetcc tgtttcacgg tctg 24
 194 <210> SEQ ID NO: 15
 195 <211> LENGTH: 24
 196 <212> TYPE: DNA
 197 <213> ORGANISM: Rattus rattus
 199 <400> SEQUENCE: 15
 200 caagacacct tgaaggcct gatg 24
 203 <210> SEQ ID NO: 16
 204 <211> LENGTH: 24
 205 <212> TYPE: DNA
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 212 <210> SEQ ID NO: 17
 213 <211> LENGTH: 33
 214 <212> TYPE: DNA
 215 <213> ORGANISM: Rattus rattus
 217 <400> SEQUENCE: 17
 218 agcgcgggccg catgaacaag tggctgtgct gcg 33

RAW SEQUENCE LISTING

DATE: 06/05/2001

PATENT APPLICATION: US/09/613,591B

TIME: 12:57:12

Input Set : A:\A-378CIP5.ST25.txt

Output Set: C:\CRF3\06052001\I613591B.raw

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221 <210> SEQ ID NO: 18
222 <211> LENGTH: 31
223 <212> TYPE: DNA
224 <213> ORGANISM: Rattus rattus
226 <400> SEQUENCE: 18
227 agctctagag aaacagccca gtgaccattc c 31
230 <210> SEQ ID NO: 19
231 <211> LENGTH: 24
232 <212> TYPE: DNA
233 <213> ORGANISM: Rattus rattus
235 <400> SEQUENCE: 19
236 gtgaagctgt gcaagaacct gatg 24
239 <210> SEQ ID NO: 20
240 <211> LENGTH: 24
241 <212> TYPE: DNA
242 <213> ORGANISM: Rattus rattus
244 <400> SEQUENCE: 20
245 atcaaaggca gggcatactt cctg 24
248 <210> SEQ ID NO: 21
249 <211> LENGTH: 24
250 <212> TYPE: DNA
251 <213> ORGANISM: Homo sapiens
253 <400> SEQUENCE: 21
254 cagatcctga agctgctcag ttg 24
257 <210> SEQ ID NO: 22
258 <211> LENGTH: 33
259 <212> TYPE: DNA
260 <213> ORGANISM: Homo sapiens
262 <400> SEQUENCE: 22
263 agcgcgccg cggggaccac aatgaacaag ttg 33
266 <210> SEQ ID NO: 23
267 <211> LENGTH: 33
268 <212> TYPE: DNA
269 <213> ORGANISM: Homo sapiens
271 <400> SEQUENCE: 23
272 agctctagaa ttgtgaggaa acagctcaat ggc 33
275 <210> SEQ ID NO: 24
276 <211> LENGTH: 39
277 <212> TYPE: DNA
OK-> 278 <213> ORGANISM: Artificial
280 <220> FEATURE:
281 <223> OTHER INFORMATION: PCR primer
283 <400> SEQUENCE: 24
284 atagcgccg ctgagcccaa atcttgtgac aaaactcac 39
287 <210> SEQ ID NO: 25
288 <211> LENGTH: 45
289 <212> TYPE: DNA
OK-> 290 <213> ORGANISM: Artificial
292 <220> FEATURE:

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RAW SEQUENCE LISTING

PATENT APPLICATION: US/09/613,591B

DATE: 06/05/2001

TIME: 12:57:12

Input Set : A:\A-378CIP5.ST25.txt

Output Set: C:\CRF3\06052001\I613591B.raw

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295 <400> SEQUENCE: 25
296 tctagagtcg acttatcatt tacccggaga caggagagg ctctt      45
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300 <211> LENGTH: 38
301 <212> TYPE: DNA
302 <213> ORGANISM: Mus musculus
304 <400> SEQUENCE: 26
305 cctctgagct caagcttccg aggaccacaa tgaacaag      38
308 <210> SEQ ID NO: 27
309 <211> LENGTH: 43
310 <212> TYPE: DNA
311 <213> ORGANISM: Mus musculus
313 <400> SEQUENCE: 27
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317 <210> SEQ ID NO: 28
318 <211> LENGTH: 38
319 <212> TYPE: DNA
320 <213> ORGANISM: Mus musculus
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323 cctctgagct caagcttccg aggaccacaa tgaacaag      38
326 <210> SEQ ID NO: 29
327 <211> LENGTH: 24
328 <212> TYPE: DNA
329 <213> ORGANISM: Homo sapiens
331 <400> SEQUENCE: 29
332 tccgtaagaa acagcccagt gacc      24
335 <210> SEQ ID NO: 30
336 <211> LENGTH: 31
337 <212> TYPE: DNA
338 <213> ORGANISM: Mus musculus
340 <400> SEQUENCE: 30
341 cctctgcggc cgctgttgca tttcctttct g      31
344 <210> SEQ ID NO: 31
345 <211> LENGTH: 19
346 <212> TYPE: PRT
347 <213> ORGANISM: Mus musculus
349 <400> SEQUENCE: 31
351 Glu Thr Leu Pro Pro Lys Tyr Leu His Tyr Asp Pro Glu Thr Gly His
352 1          5          10          15
354 Gln Leu Leu
357 <210> SEQ ID NO: 32
358 <211> LENGTH: 21
359 <212> TYPE: DNA
360 <213> ORGANISM: Mus musculus
362 <400> SEQUENCE: 32
363 tcccttgccc tgaccactct t      21
366 <210> SEQ ID NO: 33
367 <211> LENGTH: 34

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VERIFICATION SUMMARY

PATENT APPLICATION: US/09/613,591B

DATE: 06/05/2001

TIME: 12:57:13

Input Set : A:\A-378CIP5.ST25.txt

Output Set: C:\CRF3\06052001\I613591B.raw

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L:47 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:1
L:53 M:220 C: Keyword misspelled or invalid format, <213> ORGANISM for SEQ ID#:2
L:65 M:220 C: Keyword misspelled or invalid format, <213> ORGANISM for SEQ ID#:3
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L:89 M:220 C: Keyword misspelled or invalid format, <213> ORGANISM for SEQ ID#:5
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VERIFICATION SUMMARY

PATENT APPLICATION: US/09/613,591B

DATE: 06/05/2001

TIME: 12:57:13

Input Set : A:\A-378CIP5.ST25.txt

Output Set: C:\CRF3\06052001\I613591B.raw

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